BRIEF COMMUNICATION

Cancer Risk Among Women With Cosmetic Breast Implants: a Population-Based Cohort Study in Sweden

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Concerns about cancer risk after implantation of silicone devices in the human body have resulted from reports of sarcomas in silicone-exposed experimental animals and case reports of breast and other cancers in women with breast implants *(1)*. Epidemiologic data during the past few years, however, have shown no generalized increase of cancer *(1)*. In fact, the most consistent pattern observed from the investigations conducted to date has been a decreased risk of breast cancer *(1,2)*. To further evaluate the occurrence of cancers of the breast and other organs, we present findings from a large national systematic follow-up of women in Sweden who received cosmetic breast implants. This study includes a considerable increase in the number of patients and extends the follow-up time of our earlier report *(3)*.

Table 1 shows characteristics of women in the cohort who received breast implants. There were 3473 women with implants enrolled in the follow-up. As indicated in the table, the women in the cohort tended to be young (median age at cosmetic breast implant surgery was 30 years). The average duration of follow-up was 10 years, with a maximum follow-up of 29 years and a median follow-up of 9 years.

Overall, the number of women who developed cancer among implant recipients was nearly the same as expected based on national cancer rates of Swedish women of the same age over the same time period (Table 2). In total, 74 women were diagnosed with some form of cancer subsequent to implant surgery versus 70.3 expected (standardized incidence ratio [SIR] = 1.1; 95% confidence interval [CI] = 0.8–1.3). The most common was breast cancer, which occurred less often than expected (SIR = 0.7; 95% CI = 0.4–1.1), followed by cervical cancer (SIR = 1.9; 95% CI = 0.9–3.5). The only statistically significant departure from expectation was for lung cancer (SIR = 2.7; 95% CI = 1.1–5.6). There was no significant excess of lymphoproliferative/hematopoietic cancers, with one non-Hodgkin's lymphoma, one multiple myeloma, and three leukemias observed. One connective tissue cancer (an abdominal hemangiosarcoma) was diagnosed versus 0.6 expected. We observed no consistent trends in risk over time for lung, cervix, or breast cancers (data not shown).

These data add to a growing consensus that the risk of breast cancer among women with silicone breast implants is not increased and may in fact be decreased *(1,2)*. Reasons for a deficit (though not statistically significant) of breast cancer incidence are not clear, although several explanations are plausible. An anticarcinogenic effect of silicone has been postulated *(2)*, since silicone has been reported to retard *in vitro* growth of human breast cancer cells and to inhibit nitrosourea-induced breast tumors in rats *(6–9)*. More likely explanations, however, may relate to the characteristics of women with breast implants, for example, to their typically smaller breast size and less glandular tissue mass, which have been linked to a lower risk of breast cancer in some *(10)*, but not other *(11)*, studies. Furthermore, in the United States *(12)* and in Denmark *(13)*, women with breast implants have been reported to have earlier ages at the birth of their first child, a protective factor for breast cancer *(14)*. We had no information, however, on the pregnancy, menstrual, or other histories of the women in the cohort, and thus could not adjust for potential confounding factors. A clinical study *(1)* has suggested that breast implants may interfere with tumor detection, thus shifting diagnosis to a more advanced stage, but several cohort studies *(2,13,15)* have found no difference in the stages of breast cancer among implant recipients compared with those in the general population. The Swedish Cancer Register does not obtain information on stage of disease

Table 1. Characteristics of the cohort of women with breast implant surgeries[1]

Characteristic	Number (%)
No. of women[2]	3473
Person-years of follow-up	35 644
Average duration of follow-up, y	10.3
Age at surgery, y	
<25	781 (23)
25–34	1632 (47)
35–44	787 (23)
⩾45	273 (8)
Year of surgery	
⩽1976	741 (21)
1977 through 1981	622 (18)
1982 through 1986	874 (25)
⩾1987	1236 (36)

[1]Details of the design and methods of conduct of record-linkage cohort studies of implant patients in Sweden have been presented elsewhere *(3,4)*. In brief, all Swedish women listed in the national Inpatient Register (IR) with surgical procedures for cosmetic breast augmentation during the period 1965 through 1993 were identified as potentially eligible for the cohort study. Follow-up of the breast implant cohort for cancer incidence, possible by linkage with the Swedish Cancer, Migration and Death Registers (with linkage using unique personal identification numbers assigned to all Swedish residents), began 30 days after the time of surgery and continued until cancer occurrence, emigration, death, or December 31, 1993, whichever came earlier. Excluded from the cohort were all women with cancer diagnosed prior to or within 1 month of the breast implant surgery or who died or emigrated before the start of follow-up.

[2]This total was derived after excluding 4% of the potentially eligible women because of failure to find personal identification numbers in the national population registers, discrepancy between registers with respect to age or dates of migration or death, prevalent or prior cancer diagnosis, or breast implant surgery within 1 month of the end of follow-up in December 1993.

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See ''Note'' following ''References.''

Table 2. Standardized incidence ratios (SIRs) and 95% confidence intervals (CIs) for selected cancer sites among women with cosmetic breast implants[1]

Cancer	Observed	Expected	SIR	95% CI
Total	74	70.3	1.1	0.8–1.3
Digestive tract	8	8.6	0.9	0.4–1.8
Large bowel	3	4.5	0.7	0.1–2.0
Other	5	4.1	1.2	0.4–2.8
Lung	7	2.6	2.7	1.1–5.6
Skin	5	5.8	0.9	0.3–2.0
Breast	18	25.0	0.7	0.4–1.1
Reproductive system	18	13.9	1.3	0.8–2.0
Cervix	10	5.3	1.9	0.9–3.5
Ovary	6	4.6	1.3	0.5–2.8
Other	2	4.0	0.5	0.1–1.8
Brain	4	3.5	1.1	0.3–2.9
Lymphohematopoietic system	5	3.7	1.4	0.4–3.2
Hodgkin's disease	0	0.6	0.0	0.0–6.1
Non-Hodgkin's lymphoma	1	1.6	0.6	0.0–3.5
Multiple myeloma	1	0.4	2.6	0.1–14.6
Leukemia	3	1.1	2.7	0.6–7.8
Other	9	7.3	1.2	0.6–2.3

[1]Observed numbers of cancer among women in the cohort were compared with those expected based on age and calendar-specific Swedish cancer rates. SIRs were calculated as the ratios of observed to expected numbers of cancers, with 95% CIs for the SIRs calculated under Poisson assumptions *(5)*.

for breast cancer, thus we could not directly address whether implants shifted diagnoses to a later stage. However, if there was such a shift, no reduction in breast cancer mortality might be expected among the implantees. Instead, we found mortality from breast cancer among Swedish women with implants was below that of similarly aged women without implants (standardized mortality ratio = 0.5; 95% CI = 0.1–2.0), indicating no shift to a later stage of the disease at diagnosis.

Our study suggested an increase in incidence of lung and cervical cancers among the implant recipients, similar to the findings reported from a cohort study of approximately 3200 women with breast implants in Los Angeles *(2)*. Although information on smoking and lifestyle characteristics was unavailable in our cohort, it has been reported that women with implants are more likely to be smokers and have a greater number of sexual partners than women without implants *(12)* and thus may be expected to have elevated rates of lung and cervical cancers.

Sarcomas were of interest, since such tumors have arisen at the site of injection of polymers and other foreign bodies in rats *(16)*. We found only one connective tissue cancer, however, in more than 35 000 person-years of follow-up, which was close to the 0.6 cases expected, and the tumor was not adjacent to the breast implant. The findings are consistent with the lack of association between breast implants and incidence trends for sarcomas in the population *(17,18)*. Multiple myeloma and lymphoma also have been hypothesized to result from breast implants *(19–21)*, but only one woman developed multiple myeloma and another developed non-Hodgkin's lymphoma, as expected on the basis of cancer incidence rates in Sweden.

In summary, this national population-based cohort study of Swedish women with cosmetic breast implants revealed no increased risk of overall cancer. Although higher than expected numbers of cervical and lung cancer were detected, these findings appear consistent with the higher prevalence of risk factors (e.g., smoking and sexual activity) previously reported among women with breast implants. Our study showed a statistically nonsignificant reduction in the incidence of breast cancer that may be due to concomitant risk factors (e.g., lower age at first pregnancy and decreased glandular density). Further research is needed to clarify the association, if any, since the observation could be due to chance. In addition, multiple comparisons of the various observed/expected ratios can yield an occasional statistically significant observation by chance alone. However, together with other epidemiologic studies, our findings suggest that breast implants are unlikely to pose a carcinogenic risk.

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Note

Manuscript received August 25, 1997; revised November 7, 1997; accepted November 14, 1997.